Section VII: Premarket Notification 510(k) Summary

K132202
DEC - 6 2013

A. General Information on Submitter

Name:	Enthermics Medical Systems
Address:	W164 N9221 Water Street
	Menomonee Falls, WI 53051
Phone:	(262) 251-8356
Fax:	(262) 251-7067
Registered Number:	2131400
Name of contact person:	Adam Van Essen

B. General Information on the Device

Name:	DC Series Fluid Warming Cabinet
Class:	Unclassified
Product Code:	LGZ, Warmer, Thermal, Infusion Fluid

C. Predicate Device

Enthermics Medical Systems, EC-770I Fluid Warming Cabinet (K993797)

D. Device Description

The DC Series Fluid Warming Cabinets are single cavity warming cabinets intended to heat either irrigation fluids (set point range of 90°F to 150°F) or injection fluids (set point range of 90°F to 110°F). The cabinets consist of powder coated steel exterior panels, and stainless steel cavity panels. The exterior also consists of ABS plastic panels. The heating system of the device includes three or more independent, fully insulated, electrothermal arrays mounted on the outside of the cavity. The device includes an over temperature alarm which provides an audible and visual indication that the cavity temperature has exceeded the set temperature by 10°F. Additional thermal reset switches are present the shut off power to the heating array or unit in the event of an over temperature array or cavity respectively.

E. Intended Use

The Enthermics Medical Systems DC Series Fluid Warming Cabinets are designed to safely store and warm irrigation fluids and injection fluids in accordance with the recommended warming temperatures and storage times stated in the fluid manufactures' labeling.

F. Technological Characteristics of Device Compared to Predicate Device

The predicate device, the Enthermics Medical Systems EC-770I Fluid Warming Cabinet (K993797) and the new DC Series Fluid Warming Cabinets are intended for the same uses and indications and the technological features of the predicate and the new cabinets are

virtually identical. The predicate and new Cabinets share the same basic design (electrothermal heating array(s) applied to the exterior of the Cabinet cavity with forced air circulation within the cavity). They also share the same two operational mode specifications (for injection and irrigation mode temperature ranges), and use the same over-temperature alarm systems (audible and visual indicators if set point is exceeded by a designated temperature).

The chief differences between the predicate and the new cabinet models include a smaller volume capacity for the new cabinets, the use of powder coated stainless steel panels and interior baskets and of external ABS plastic panels for the new cabinet exterior; two more electrothermal arrays in the new cabinets; and more accurate temperature detection and control.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

Enthermics Medical Systems
Mr. Adam Van Essen
Project Coordinator
W164 N9221 Water Street
MENOMONEE FALLS Wisconsin 53051

Re: K132202
Trade/Device Name: DC Series Fluid Warming Cabinet (DC250L and DC400L)
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LGZ
Dated: November 4, 2013
Received: November 4, 2013

Dear Mr. Van Essen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer
-S for

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132202

Device Name
DC Series Fluid Warming Cabinets

Indications for Use *(Describe)*

The Enthermics Medical Systems DC Series Fluid Warming Cabinets are designed to store and warm irrigation fluids and injection fluids in accordance with the recommended warming temperatures and storage times stated in the fluid manufacturers' labeling.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2013.12.06 10:02:49 -05'00'